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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,389	08/25/2000	David Pinsky	62683/JPW/JML	5890

7590 08/16/2004

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/648,389	PINSKY ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

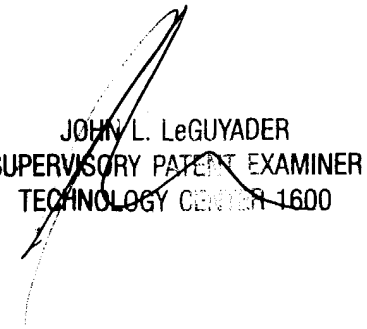
   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *16,18-20,22-30 and 32-36*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Claims 16, 18-20, 22-30, and 32-36 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing ischemic damage to a lung tissue being transplanted into a subject comprising contacting the tissue with SEQ ID NO: 1 ex vivo, does not reasonably provide enablement for a method for reducing ischemic damage to a tissue being transplanted into a subject comprising contacting the tissue with any nucleic acid which inhibits the expression of Egr-1. In response to this rejection, Applicants argue that the instant specification enables a person skilled in the art to use the invention commensurate in scope with the claims. Specifically, Applicants argue based on the art at the time of filing, identifying additional nucleic acids (i.e. antisense) capable of inhibitng Egr-1 expression would not have required undue experimentation. Applicants rely on Smith et al. This argument is not found persuasive, because the issue of the instant rejection is not identifying additional antisense capable of inhibiting Egr-1 expression, and whether this identification requires undue experimentation. Instead, and as discussed in the previous Office Action mailed February 17, 2004, the issue is whether other antisense capable of inhibiting Egr-1 expression will reduce vascular tissue injury during reperfusion of an ischemic tissue in a subject, as contemplated in the instant specification, where the application as filed has only described SEQ ID NO:1, and the art has taught antisense nucleic acid therapy is highly unpredictable. Applicants also argue that based on the instant specification and the art at the time of filing, one skilled in the art would have been able to deliver an effecitve amount of antisense to a desired location within a subject in order to inhibit RNA expression in vivo without undue experimentation. Applicants rely on Exhibit B, Morishita et al. This argument is not found persuasive because Exhibit B relies upon a reference that uses compositions not supported by the instantly filed specification. Such reference does not provide evidence of enablement at the time of filing of the invention unless supported by the instant specification and therefore is not found persuasive. Further, Morishita et al. provide evidence regarding the unpredictability of antisense nucleic acids at page 921, last paragraph where ACE antisense oligonucleotides partially inhibited neointimal formation, whereas previous findings with cell cycle regulatory genes showed almost complete inhibition. This demonstrates that in vivo findings for one specific antisense oligonucleotide cannot be applied to another totally different antisense oligonucleotide, but instead, must be considered on a case-by-case basis, in view of the unpredictability of antisense therapy. Applicant's argument as to the state of the art at the time of filing appears merely to be an opinion that is not persuasive, given the well-known unpredictability of the state of the art.



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